IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,	)	
	)	
Defendants.	)	
	)	

COMPLAINT

Plaintiff Meda Pharmaceuticals Inc. ("Meda" or "Plaintiff"), by its attorneys, for its Complaint against Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,071,073 ("the '073 patent"), 8,518,919 ("the '919 patent"), and 9,919,050 ("the '050 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to Abbreviated New Drug Application ("ANDA") No. 212775, filed by Aurobindo with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Astepro® (azelastine hydrochloride) nasal spray, 0.15%, EQ 0.1876 mg base/spray, prior to the expiration of the '073, '919, and '050 patents.

THE PARTIES

2. Plaintiff Meda is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

3. On information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having a registered office at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad – 500038, Telangana, India, and a corporate office at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad – 500084, Telangana, India.

4. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton-Highstown Road, East Windsor, New Jersey 08520.

5. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited.

6. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. are acting cooperatively with respect to ANDA No. 212775.

7. On information and belief, Aurobindo Pharma USA, Inc. acts as the U.S. agent of Aurobindo Pharma Limited for ANDA No. 212775.

8. On information and belief, Aurobindo, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and/or sells generic drug products for sale and use throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited. Aurobindo Pharma USA, Inc. also has its principal place of business in the State of New Jersey.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. 1400(b).

THE PATENTS-IN-SUIT

12. The ’073 patent, titled “Compositions comprising azelastine and methods of use thereof,” was duly and legally issued by the U.S. Patent and Trademark Office (“USPTO”) on December 6, 2011. A true and correct copy of the ’073 patent is attached as Exhibit A.

13. As set forth in greater detail in the ’073 patent, the claims of the ’073 patent are directed to, *inter alia*, methods of treating a physical disorder and liquid pharmaceutical compositions comprising azelastine hydrochloride.

14. Meda Pharmaceuticals Inc. is the assignee of the ’073 patent.

15. The ’919 patent, titled “Compositions comprising azelastine and methods of use thereof,” was duly and legally issued by the USPTO on August 27, 2013. A true and correct copy of the ’919 patent is attached as Exhibit B.

16. As set forth in greater detail in the ’919 patent, the claims of the ’919 patent are directed to, *inter alia*, liquid pharmaceutical compositions comprising azelastine hydrochloride.

17. Meda Pharmaceuticals Inc. is the assignee of the ’919 patent.

18. The ’050 patent, titled “Compositions comprising azelastine,” was duly and legally issued by the USPTO on March 20, 2018. A true and correct copy of the ’050 patent is attached as Exhibit C.

19. As set forth in greater detail in the ’050 patent, the claims of the ’050 patent are directed to, *inter alia*, liquid intranasal compositions comprising azelastine hydrochloride.

20. Meda Pharmaceuticals Inc. is the assignee of the ’050 patent.

21. Meda, as the assignee of the '073, '919, and '050 patents (collectively, "the Patents-in-Suit"), owns the entire right, title, and interest in each of the Patents-in-Suit. Meda has the right to enforce each of these Patents.

22. On October 15, 2008, FDA approved New Drug Application ("NDA") No. 022203 for azelastine hydrochloride nasal spray, 0.15%, 205.5 mcg per spray (the "Astepro® NDA"), which is marketed under the name Astepro® in the United States.

23. Astepro® is indicated for the treatment of allergic rhinitis, including relief of the symptoms of seasonal and perennial allergic rhinitis. The approved uses of Astepro® are described in the Astepro® Prescribing Information.

24. The '073, '919, and '050 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as covering Astepro® and one or more of its approved uses under NDA No. 022203.

ACTS GIVING RISE TO THIS ACTION

25. In a letter dated January 3, 2019, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Notice Letter"), Aurobindo notified Meda that it had submitted to FDA ANDA No. 212775 with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the azelastine hydrochloride nasal spray, 0.15%, 205.5 mcg per spray, described in ANDA No. 212775 (the "ANDA Product"), as a generic version of Astepro®, prior to the expiration of the '073, '919, and '050 patents.

26. In the Notice Letter, Aurobindo states that ANDA No. 212775 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '073, '919, and/or '050 patents are invalid under 35 U.S.C. § 103.

27. Aurobindo had knowledge of the '073, '919, and/or '050 patents when it submitted and filed ANDA No. 212775.

28. This action is being commenced within 45 days of receipt of the Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,071,073

29. Plaintiff repeats and realleges the allegations of paragraphs 1-28 as if fully set forth herein.

30. Aurobindo's submission of ANDA No. 212775 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in/into the United States prior to the expiration of the '073 patent constitutes infringement of one or more claims of the '073 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

31. Aurobindo had knowledge of the '073 patent when it submitted ANDA No. 212775. Aurobindo's infringement has been, and continues to be, deliberate.

32. Plaintiff will be substantially and irreparably harmed if Aurobindo's infringement of the '073 patent is not enjoined. Plaintiff does not have an adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 8,518,919

33. Plaintiff repeats and realleges the allegations of paragraphs 1-32 as if fully set forth herein.

34. Aurobindo's submission of ANDA No. 212775 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in/into the United States prior to the

expiration of the '919 patent constitutes infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

35. Aurobindo had knowledge of the '919 patent when it submitted ANDA No. 212775. Aurobindo's infringement has been, and continues to be, deliberate.

36. Plaintiff will be substantially and irreparably harmed if Aurobindo's infringement of the '919 patent is not enjoined. Plaintiff does not have an adequate remedy at law.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 9,919,050

37. Plaintiff repeats and realleges the allegations of paragraphs 1-36 as if fully set forth herein.

38. Aurobindo's submission of ANDA No. 212775 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product in/into the United States prior to the expiration of the '050 patent constitutes infringement of one or more claims of the '050 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

39. Aurobindo had knowledge of the '050 patent when it submitted ANDA No. 212775. Aurobindo's infringement has been, and continues to be, deliberate.

40. Plaintiff will be substantially and irreparably harmed if Aurobindo's infringement of the '050 patent is not enjoined. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment that Aurobindo has infringed one or more claims of the '073, '919, and/or '050 patents by the filing of ANDA No. 212775;

(b) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 212775 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '073, '919, and/or '050 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(c) Injunctive relief preliminarily and permanently enjoining Aurobindo, whether alone or through a subsidiary company, from making, using, selling, offering for sale, or importing the ANDA Product in/into the United States until after expiration of the '073, '919, and/or '050 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(d) Costs and expenses in this action; and

(e) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

CRITCHLEY, KINUM & DENOIA, LLC

OF COUNSEL:

Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
Tel: (212) 940-8800

Jitendra Malik, Ph.D.
Alissa Pacchioli
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28202-4213
Tel: (704) 444-2000

By: */s/ Amy Luria*
Amy Luria
CRITCHLEY, KINUM & DENOIA, LLC
75 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 422-9200
Fax: (973) 422-9700
aluria@critchleylaw.com

Dated: February 12, 2019